IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: G. CONNOR

Serial No.: NOT YET ASSIGNED Art Unit: NOT YET ASSIGNED

Filed : January 23, 2004 Examiner: NOT YET ASSIGNED

FOr : COMBINATION THERAPY COMPRISING ANTI-DIABETIC AND

ANTICONVULSANT AGENTS

I hereby certify that this correspondence is being deposited with the United States Postal Service as express mail in an envelope addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

January 23, 2004 (Date of Deposit)

MARY A. APPOLLINA (Name of applicant, assignee, or Registered Representative)

JANUARY 23, 2004

(Date of Signature)

Mail Stop Patent Application Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this

information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

In accordance with §1.97(b), since this Information \boxtimes Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in $\S1.491$, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required. In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with [] the first or Second After Final Submission, therefore: Statement in Accordance with §1.97(e) (attached); or Please charge Deposit Account No. 10the fee of \$180.00 as set forth

In accordance with §1.97(c), this Information
Disclosure Statement is being filed after the period set forth
in §1.97(b) above but before the mailing date of either a Final
Action under §1.113 or a Notice of Allowance under §1.311, or an
action that otherwise closes prosecution and that it is
accompanied by one of:

in $\S1.17(p)$.

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☐ In	accordance with §1.97(d), this Information
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under § 1.311	but before the payment of the Issue Fee.
Applicant(s)	hereby petition(s) for consideration of this
Information D	Disclosure Statement. Included are: Statement in
Accordance wi	th §1.97(e) as set forth below and the fee of
	et forth in § 1.17(p).
	3
⊠ Cor	oies of each of the references listed on the
attached Form	PTO-1449 are enclosed herewith with the exception
of J. Marks,	the Insulin Resistance Syndrome, The Monitor,
1(3), Spring	1996, which was cited by the Office in the parent
application 1	.0/042,425 filed October 25, 2001, relied on for an
	tive filing date under 35 U.S.C.§120.
☐ Cor	oies of references listed on the attached Form PTO-
1449 are encl	osed herewith EXCEPT THAT:
	In view of the voluminous nature of references
	[list as appropriate], and the likelihood that
	these references are available to the Examiner,
	copies are not enclosed herewith.
	If any of the foregoing publications are not
_	available to the Examiner, Applicant will
,	endeavor to supply copies at the Examiner's
·	request.
	-

Copies of only forei	gn patent documents and non-
patent literature are enclosed	in accordance with 37 CFR 1.98
(a)(2). (The U.S. patents and	each U.S. patent application
publication listed on the atta	ched Form PTO-1449 are not
enclosed because this U.S. pat	ent application was filed after
June 30, 2003 or this internat	ional application has entered the
national stage under 35 USC §3	71 after June 30, 2003 (see USPTO
waiver of requirement under 37	CFR 1.98 (a)(2)(i).
∑ There are no listed	references which are not in the
English language.	
☐ The relevance of the	se listed references which are
not in the English language is	as follows:
	of search report(s) from
corresponding patent applicati	on(s), which are listed on the
attached Submission Under MPEP	9 609 D.
Attached are the fol	lowing non-published pending
patent applications which may	be deemed relevant, which are
listed on the attached Submiss	ion Under MPEP 609 D.
Please charge any deficie	ency or credit any overpayment to
Deposit Account No. 10-0750/OR	T-1520-USA-CNT/MAA. This form is
submitted in triplicate.	
	Respectfully submitted,
	Mary A. Appollina
	Reg. No. 34,087
	Attorney for Applicants

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-3742 DATED: January 23, 2004

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1	Application Number	NOT YET ASSIGNED			
	Filing Date	JANUARY 23, 2004			
	First Named Inventor	G. CONNOR			
	Group Art Unit	NOT YET ASSIGNED			
	Examiner Name	NOT YET ASSIGNED			
	Attorney Docket Number	ORT-1520-USA-CNT			
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				U.S. PATENT DOCUMENTS		
Examiner Initials	Cite No.1			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appea
		4,513,006		Maryanoff et al	04/23/1985	
		5,242,942		Costanzo et al	009/07/1993	
		5,384,327		Costanzo et al	01/24/1995	
		5,387,700		Maryanoff et al	02/07/1995	
		6,071,537		Shank	06/06/2000	
		6,130,216		Antonucci et al	10/10/2000	
		6,191,163	B1	Cottrell	02/20/2001	
						A
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FOREIGN PATENT DOCUMENTS Date of Publication Pages, Columns, Lines, Foreign Patent Document of Cited Document where relevant Name of Patentee or passages or relevant Examiner Cite mm-dd-yyyy Applicant of Cited Document figures appear Initials KindCode⁵ Office³ Number⁴ No.1 Ortho-McNeil Pharmaceutical, Inc. 09/10/1999 wo 99/44581 A2 wo 00/50020 A2 University of Cincinnati 08/31/2000 Α1 10/12/2000 wo 00/59506 Bristol Myers Squibb Co. 10/19/2000 wo 00/61139 Α1 Ortho-McNeil Pharmaceutical, Inc wo 00/61140 Α1 Ortho-McNeil Pharmaceutical, Inc. 10/19/2000 wo 00/76493 Α1 Naiarian 12/21/2000 04/19/2001 wo 01/27128 A1 Bristol Myers Squibb Co.

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¹ Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document, s Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. e Applicant is to place a check mark here if English language Translation is attached.

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G. CONNOR			
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		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner's Initials*	Cite No.1	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
		OSBORNE et al, Topiramate Improves Glycemic Control and Triglycerides in Animal Models, Presented to ADA. Abstracts published on line http://www.diabetes.org/am01/AnnualMeeting/Abstracts/AbstractSearch.asp pp 1-11 Abstract.	
		OSBORNE Figures 6 pages	
		DEMAREST, K. ET AL Topiramate Improves Tolerance and May Improve Insulin Sensitivity in Animal Models of Type 2 Diabetes Mellitus. Pages 1-10. Abstract	
		DEMAREST POSTER 6 PAGES Figure 1a to Figure 4	
		CROOKE et al. ABSTRACT, Topiramate Improves Glycemic Control Independent of Weight Loss in ob/ob Mice 1 page	
		DEMAREST ET AL ABSTRACT Topinnate Improves Glucose Tolerance and May Improve Insulin Sensitivity in Animal Models of Type 2 Diabetes Mellitus 1 page	
		MARKS, Jennifer B., The Insulin Resistance Syndrome, The Monitor, Volume 1, No. 3, Spring 1996.	
		OSBORNE ET AL ABSTRACT Topiramate Improves Glycemic Control and Triglycerides in Animal Models 1 page The Posters were presented at the Amierican Diabetes Association Conference held June 22-26 in Philadelphia	
		SMITH, ULF ET AL, Topiramate, a novel antiepileptic drug, reduces body weight and food intake in obesity. 1 page Published in Obesity Research Volume 8 (Suppl. 1) Oct 2000	

Examiner	Date	i i
Examino		I I
Signature	Considered	

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SUBMISSION UNDER MPEP 609 D

Application Number NOT YET ASSIGNED
Filing Date JANUARY 23, 2004
First Named Inventor G. CONNOR
Group Art Unit NOT YET ASSIGNED
Examiner Name NOT YET ASSIGNED
Attorney Docket Number ORT-1520-USA-CNT

Page 1 of 1

		U.S. PA	TENT DOCUMENTS		
			U.S. Patent Docum	ent	Pages, Columns, Lines, where relevant passages or relevant figures appear
Examiner Cite Initials No.1		Name of Patentee or Applicant of Cited Document	Number	Kind Code ² (if known)	
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		OTHER PRIOR ART -	NON PATEN	T LITERATUR	RE DOCUME	NTS	·
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THUCK!		PCT Search Report for PCT/US 01/50	0840 dated No	ovember 13, 2	2002		
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